TORNIER
Implants Chirurgicaux

Summary of Safety and Effectiveness information

510(k) Premarket Notification – Aequalis Shoulder Fracture System, Aequalis Reversed Shoulder Prosthesis, Aequalis Reversed Fracture Shoulder Prosthesis, Aequalis Resurfacing Head

Date prepared: September 9th 2013

OCT 16 2013

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	***Aequalis Shoulder Fracture System***
Common name:	Hemi or Total Shoulder Prosthesis
Classification name:	§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

Trade name:	***Aequalis Reversed Shoulder Prosthesis***
Common name:	Total Shoulder Prosthesis
Classification name:	§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis § 888.3690 Shoulder, Hemi-, Humeral, Metallic uncemented

Trade name:	***Aequalis Reversed Fracture Shoulder Prosthesis***
Common name:	Total Shoulder Prosthesis
Classification name:	§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

Trade name:	***Aequalis Resurfacing Head***
Common name:	Humeral Resurfacing Head
Classification name:	§ 888.3690 Shoulder joint, humeral (hemi-shoulder), metallic uncemented prosthesis

2) Submitter

Tornier SAS
161, Rue Lavoisier
38330 Montbonnot Saint Martin - France

3) Applicant

Tornier SAS
161, rue Lavoisier
38330 Montbonnot Saint Martin - France

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S.A.S. au capital de 35 043 008 €
SIRET : 070 501 275 000 21
R.C.S. : 070 501 275
CODE APE : 3250 A

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4) Company contact

Tornier SAS
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Project Regulatory Affairs Coordinator
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5) Classification

For the Aequalis Shoulder Fracture System:
Device class: Class II
Classification panel: Orthopedic
Product code: KWS

For the Aequalis Reversed Shoulder Prosthesis:
Device class: Class II
Classification panel: Orthopedic
Product code: KWS & HSD

For the Aequalis Reversed Fracture Shoulder Prosthesis:
Device class: Class II
Classification panel: Orthopedic
Product code: KWS

For the Aequalis Resurfacing Head:
Device class: Class II
Classification panel: Orthopedic
Product code: HSD

6) Equivalent / Predicate device

For the Aequalis Shoulder Fracture System:
Aequalis Shoulder Fracture system, Tornier, K060209

For the Aequalis Reversed Shoulder Prosthesis:
Aequalis Reversed Shoulder Prosthesis, Tornier, K100142

For the Aequalis Reversed Fracture Shoulder Prosthesis:
Aequalis Reversed Fracture Shoulder System, Tornier, K082120

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For the Aequalis Resurfacing Head:
Aequalis Resurfacing Head, Tornier, K062661

7) Device description

For the Aequalis Shoulder Fracture System:
The usual goal of total shoulder replacement and hemi-arthroplasty of the shoulder is to restore the shoulder joint to its best working condition and to reduce or eliminate pain. The Aequalis Shoulder Fracture System is intended to accomplish these goals. With the Aequalis Shoulder Fracture System, the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury. Thus the Aequalis Shoulder Fracture System is intended for use as a total shoulder replacement system, or as a hemi-shoulder. The modular nature of the system allows for the later conversion of a primary hemi-arthroplasty to a total shoulder replacement.

For the Aequalis Reversed Shoulder Prosthesis:
The Aequalis Reversed Shoulder Prosthesis is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional. Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The Aequalis Reversed Shoulder Prosthesis is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.
The Aequalis Reversed Shoulder Prosthesis is a semi-constrained system composed of a humeral and a glenoid parts.

For the Aequalis Reversed Fracture Shoulder Prosthesis:
The Aequalis Reversed Fracture Shoulder Prosthesis is intended to be used to relieve pain or significant disability following massive cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.

Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The Aequalis Reversed Fracture Shoulder Prosthesis is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm and its Aequalis Fracture Shoulder humeral stem-like design allows to facilitate the bone reconstruction and improve the tuberosity healing and fixation.
The Aequalis Reversed Fracture Shoulder Prosthesis is a semi-constrained system composed of a humeral and a glenoid parts.

For the Aequalis Resurfacing Head:
The Aequalis Resurfacing Head is a humeral head resurfacing device. It requires less bone and cartilage removal, which makes it much more conservative than total joint implants. Revision or arthrodesis can be undertaken easily because the bone stock has been maintained with no loss of

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length. The main advantages of humeral head resurfacing are preservation of bone and the relatively simple surgical technique.

With the Aequalis Resurfacing Head the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury.

The present submission corresponds to the following modification:

- Addition of a new coating subcontractor (hydroxylapatite coating and titanium + hydroxylapatite coating): Eurocoating S.p.A on cobalt chromium and titanium components.

All the prostheses of this application are strictly identical to the previously cleared devices except for the coating supplier. The indications for use of each device are not modified.

8) Materials (modified components)

For the Aequalis Shoulder Fracture System:
The humeral implant is manufactured from titanium alloy (Ti6Al4V) in accordance with ISO standard 5832-3.
The hydroxylapatite coating conforms to the ASTM standard F 1185.

For the Aequalis Reversed Shoulder Prosthesis:
The uncemented stem is manufactured from titanium alloy (Ti6Al4V) in accordance with ISO standard 5832-3. The metaphysis is manufactured from cobalt-chromium alloy in accordance with ISO standard 5832-4 and ultra high molecular weight polyethylene (UHMWPE) in accordance with ISO standard ISO5834-2. The baseplate of the glenoid implant is manufactured from titanium alloy (Ti6Al4V) in accordance with ISO standard 5832-3.
The hydroxylapatite coating conforms to ASTM standard F 1185.

For the Aequalis Reversed Fracture Shoulder Prosthesis:
The uncemented stem is manufactured from titanium alloy (Ti6Al4V) in accordance with ISO standard 5832-3.
The hydroxylapatite coating conforms to ASTM standard F 1185.

For the Aequalis Resurfacing Head:
The resurfacing head is manufactured from Cobalt-Chromium alloy according to ISO 5832-4. The bone contacting surfaces are coated with titanium plasma spray according to ASTM F1580 and hydroxylapatite according to ASTM F1185.

9) Indications

Aequalis Shoulder Fracture System & Aequalis Resurfacing Head:

Aequalis Range :
Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture

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- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed.

Aequalis monobloc stem is for uncemented use only.
The Aequalis press-Fit stem is for uncemented use only.
The glenoid component is for cemented use only.

Aequalis Fracture range:
- Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures.
- Revisions when other devices or treatments have failed.

The Aequalis fracture stem is for cemented use only.
The glenoid component is for cemented use only.

Aequalis Resurfacing Head range:
The resurfacing implant is indicated as a total or hemi shoulder joint replacement where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable.
The replacement of the joint with this device is indicated to relieve severe pain or significant disability caused by degenerative pathologies: osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, primary and secondary necrosis of the humeral head.

The resurfacing implant is intended for uncemented use only.
The glenoid component is for cemented use only.

Aequalis Reversed Shoulder Prosthesis

Cemented Aequalis Reversed prosthesis:
It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated with the massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.
When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.
When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.
Uncemented Aequalis Reversed prosthesis:
It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. The humeral components are for non-cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

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When during the primary surgery the glenoid stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.
When, in case of revision of an Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Aequalis Reversed Fracture Shoulder Prosthesis

The Aequalis Reversed Fracture Shoulder Prosthesis is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain or significant disability following arthropathy associated to a grossly deficient rotator cuff joint:

- in case of traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures, or
- in case of bone defect in proximal humerus.

The Aequalis Reversed Fracture Shoulder Prosthesis is also indicated for prosthetic revisions with a grossly deficient rotator cuff joint when other treatments or devices have failed.
When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemiprosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed Fracture Shoulder Prosthesis into a non reversed hemi-prosthesis.
When, in case of revision of a Aequalis Reversed Fracture Shoulder Prosthesis, the glenoid bone stock appears to be insufficient to implant a base plate and a sphere of Aequalis Reversed range again, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed Fracture Shoulder Prosthesis into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

The Aequalis Reversed Fracture Shoulder humeral stem is used in association with the glenoid components of the Aequalis Reversed Shoulder Prosthesis.

The Aequalis Reversed Fracture Shoulder humeral stem is for cemented use only.

10) Summary of technological characteristics

The only change to the cleared devices of the *Aequalis Shoulder Fracture System*, the *Aequalis Reversed Shoulder Prosthesis*, the *Aequalis Reversed Fracture Shoulder Prosthesis* and the *Aequalis Resurfacing Head* is the addition of a new coating subcontractor: Eurocoating S.p.A
The Eurocoating S.p.A coating has the same specifications currently requested from BioCoat Company: coating specification drawings as well as the intended use of the coating of the implants concerned are not modified compared to the already cleared devices.
Process specifications for the application of hydroxylapatite coating, titanium + hydroxylapatite coating have been provided in Eurocoating S.p.A Master Files MAF 2114, MAF 2119 and MAF 2144.

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The indications for use, the other technical characteristics (design, materials, manufacturing, sizing, method of fixation) of the *Aequalis Shoulder Fracture System*, the *Aequalis Reversed Shoulder Prosthesis*, the *Aequalis Reversed Fracture Shoulder Prosthesis* and the *Aequalis Resurfacing Head* are identical to the predicate devices. The covered zones of the implants concerned remain the same ones

11) Non-clinical testing & Substantial equivalence conclusion

Non-clinical testing (shear fatigue strength, static shear strength test, static tensile strength and abrasion) and coating characterization (thickness, pore size and pore volume) were performed on the coating to determinate substantial equivalence.

The design, the material, the sizes, the method of fixation and the sterilization process are identical for devices whatever the coating subcontractor is.

The results of this evaluation allow us to conclude that the proposed new coating subcontractor Eurocoating S.p.A described in this submission does not induce any new or higher risk compared to the predicate coating subcontractor BioCoat Company and therefore both coating subcontractors (proposed and predicate) are substantially equivalent.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 16, 2013

TORNIER SAS
Ms. Séverine Bonneton
Project Regulatory Affairs Coordinator
161 Rue Lavoisier
Montbonnot Saint Martin, Isere 38334
FRANCE

Re: K131231
Trade/Device Name: Aequalis Shoulder Fracture System
Aequalis Reversed Shoulder Prosthesis
Aequalis Reversed Fracture Shoulder Prosthesis
Aequalis Resurfacing Head
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: September 19, 2013
Received: September 20, 2013

Dear Ms. Bonneton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131231

Device Name: Aequalis Shoulder Fracture System
Aequalis Reversed Shoulder Prosthesis
Aequalis Reversed Fracture Shoulder Prosthesis
Aequalis Resurfacing Head

Indications For Use:

Aequalis Shoulder Fracture System & Aequalis Resurfacing Head:

Aequalis Range :
Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis. Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed.

Aequalis monobloc stem is for uncemented use only.
The Aequalis press-Fit stem is for uncemented use only.
The glenoid component is for cemented use only.

Aequalis Fracture range:
- Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures.
- Revisions when other devices or treatments have failed.

The Aequalis fracture stem is for cemented use only.
The glenoid component is for cemented use only.

Aequalis Resurfacing Head range:
The resurfacing implant is indicated as a total or hemi shoulder joint replacement where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable.
The replacement of the joint with this device is indicated to relieve severe pain or significant disability caused by degenerative pathologies: osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, primary and secondary necrosis of the humeral head.

The resurfacing implant is intended for uncemented use only.
The glenoid component is for cemented use only.

Aequalis Reversed Shoulder Prosthesis

Cemented Aequalis Reversed prosthesis:
It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated with the massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.
When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Uncemented Aequalis Reversed prosthesis:
It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. The humeral components are for non-cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.
When during the primary surgery the glenoid stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.
When, in case of revision of an Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Aequalis Reversed Fracture Shoulder Prosthesis

The Aequalis Reversed Fracture Shoulder Prosthesis is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain or significant disability following arthropathy associated to a grossly deficient rotator cuff joint:

- in case of traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures, or
- in case of bone defect in proximal humerus.

The Aequalis Reversed Fracture Shoulder Prosthesis is also indicated for prosthetic revisions with a grossly deficient rotator cuff joint when other treatments or devices have failed.
When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemiprosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed Fracture Shoulder Prosthesis into a non reversed hemi-prosthesis.
When, in case of revision of a Aequalis Reversed Fracture Shoulder Prosthesis, the glenoid bone stock appears to be insufficient to implant a base plate and a sphere of Aequalis Reversed range again, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed Fracture Shoulder Prosthesis into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

The Aequalis Reversed Fracture Shoulder humeral stem is used in association with the glenoid components of the Aequalis Reversed Shoulder Prosthesis.

The Aequalis Reversed Fracture Shoulder humeral stem is for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices